



K073313

JAN 02 2007

## **510(k) Summary**

**Submitter:** OmniGuide, Inc.  
One Kendall Square, Building 100 3<sup>rd</sup> Floor  
Cambridge, MA 02139

**Contact Person:** Douglas W. Woodruff  
**Telephone:** 617-551-8404

**Fax:** 617-551-8445

**Proprietary Name:** OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber  
with Low Profile Tip

**Common Name:** CO<sub>2</sub> Laser Powered Surgical Instrument

**Classification:** 878.4810

**Product Code:** GEX

**Classification Name:** Laser surgical instrument for use in general and plastic  
surgery and in dermatology.

### **Substantial Equivalence Claimed To:**

K050541, OmniGuide Beam Path CO<sub>2</sub> Mark I Laser Beam Delivery System  
K070157, OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber

**Description:**

The OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber with Low Profile Tip is an accessory for CO<sub>2</sub> laser systems. It consists of a flexible fiber assembly that delivers CO<sub>2</sub> laser energy that enables minimally invasive surgery. OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber with low profile metal tip is supplied sterile and is intended for single procedure use in conjunction with the OmniGuide Laser Adapter.

**Intended Use:**

The OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber with Low Profile Tip is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology, otorhinolaryngology, gastroenterology, neurosurgery, urology, and pulmonology, and can be used in open surgical procedures as well as endoscopic minimally invasive procedures in conjunction with rigid or flexible endoscopes, such as in laryngoscopy, gastroscopy, colonoscopy, laparoscopy, thoracoscopy, hysteroscopy and bronchoscopy.

The indications for use for which the delivery system is used for are dependent upon the cleared indications for use of the laser system and those laser system accessories to which it is attached.

**Summary of Technological Characteristics:**

The device consists of an optical fiber assembly. The main functional component of the fiber assembly is a photonic bandgap reflector lining its hollow core that reflects and thereby guides CO<sub>2</sub> laser energy and a stainless steel waveguide distal tip. The fiber assembly is 1 to 2 m long and transmits at the CO<sub>2</sub> laser emission wavelength of 10.6 μm. The fiber has 14 mm long stainless steel tip that is used as a continuation of the waveguide, which enhances visualization in tight areas.

**Performance Data:**

Non-clinical Performance Data: The OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber with Low Profile Tip performance characteristics have been evaluated through testing and analysis of laser power output and beam quality. This type of testing complies with the respective section of the FDA Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (1995) and is similar to the predicate device tests. The performance of OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber with Low Profile Tip and the related parameters of the predicate devices are comparable.

Clinical Performance Data: Formal clinical trials were not deemed necessary as the device is using the same technology and intended use as the predicate devices.

**Conclusions Drawn from Tests and Analysis:** The intended use and major performance parameters (energy transmission levels and beam quality) of the OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber with Low Profile Tip are similar or equivalent to the characteristics of above mentioned legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

OmniGuide, Inc.  
% Regulatory Technology Services  
Mr. Mark Job  
1394 25<sup>th</sup> Street, NW  
Buffalo, MN 55313

JAN - 2 2008

Re: K073313

Trade/Device Name: OmniGuide Beam Path CO<sub>2</sub> Mark III WageGuide Fiber  
With Low Profile Tip

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and  
Plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: December 15, 2007

Received: December 17, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Mark Job

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): Not yet assigned

Device Name: OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber  
with Low Profile Tip

### Indications For Use:

The OmniGuide Beam Path CO<sub>2</sub> Mark III WaveGuide Fiber with Low Profile Tip is indicated for the incision, excision, ablation, vaporization and coagulation of body soft tissues including intra-oral tissues. It is indicated in the medical specialties of general and plastic surgery, oral/maxillofacial surgery, dentistry, dermatology, gynecology, otorhinolaryngology, gastroenterology, neurosurgery, urology, and pulmonology, and can be used in open surgical procedures as well as endoscopic minimally invasive procedures in conjunction with rigid or flexible endoscopes, such as in laryngoscopy, gastroscopy, colonoscopy, laparoscopy, thoracoscopy, hysteroscopy and bronchoscopy.

The indications for use for which the delivery system is used for are dependent upon the cleared indications for use of the laser system and those laser system accessories to which it is attached.


Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

 FOR M. NELKERSON  
(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

Page 1 of   1  

510(k) Number   K073313